

CLAIMS

We claim:

1. An apparatus for automatically fixing sutures used in the surgical replacement of a heart valve, comprising:

5 a first cylinder having a first end and a second end and an interior surface and an exterior surface;

a valve sleeve comprising an annular cuff and a plurality of securing struts surrounding said exterior surface adjacent to said first end of said first cylinder, said struts extending beyond said first end of said first cylinder;

10 first securing means formed on said exterior surface adjacent to said second end of said first cylinder;

a replacement heart valve positioned within said valve sleeve and having a circumferential outer edge, wherein said circumferential outer edge is affixed to said valve sleeve;

15 a second cylinder having second securing means formed on an interior surface of said second cylinder, such that said second securing means corresponds to and is adapted to fixedly engage said first securing means.

2. The apparatus of claim 1, wherein said first securing means is an annular lip and said second securing means is an annular groove.

20 3. The apparatus of claim 1, wherein said first securing means is an annular groove and said second securing means is an annular lip.

4. The apparatus of claim 1, wherein said valve sleeve is manufactured from a surgical fabric.

5. The apparatus of claim 4, wherein said surgical fabric is selected from the group
25 consisting of a Dacron® fabric, a Teflon® fabric, a Gore-Tex® fabric, and the like.

6. The apparatus of claim 1, wherein said replacement heart valve comprises a heart valve harvested from a human donor.

7. The apparatus of claim 1, wherein said replacement heart valve comprises a heart valve harvested from a pig.

30 8. The apparatus of claim 1, wherein said replacement heart valve comprises a prosthetic heart valve.

9. The apparatus of a claim 1, further comprising:

a guiding rod including a rod end piece formed at a first end of said rod, said rod end piece having a plurality of support brackets extending from said rod end piece and a guiding ring affixed to said support brackets, said ring being adapted to engage said second end of said first cylinder, wherein said interior surface of said second cylinder slidingly engages an exterior surface of each of said support brackets;

a securing member including a rod sleeve which slidingly engages said guiding rod, and a sleeve end piece formed on a first end of said rod sleeve, said sleeve end piece having plurality of securing brackets, which are adapted to engage said second cylinder and which are positioned to interfit with said support brackets; and

urging means for sliding said securing member on said guiding rod, whereby said second securing means of said second cylinder are urged into engagement with said first securing means on said first cylinder.

10. The apparatus of claim 9, wherein said urging means comprises a handle, said handle affixed to a second end of said guiding rod and including a grip having a levered projection, such that when said grip is pressed against said handle, said levered projection contacts said securing member and urges said securing member toward said rod end piece.

11. The apparatus of claim 9, wherein at least one eyelet is formed on each of said supporting brackets for receiving at least one suture, whereby said guiding ring is guided into contact with said second end of said first cylinder.

12. An apparatus for automatically fixing sutures used in the surgical replacement of a heart valve, comprising:

a first cylinder having a first end and a second end and an interior surface and an exterior surface, a valve sleeve including an annular cuff, and a prosthetic heart valve positioned within said first cylinder and affixed to said valve sleeve;

wherein said sleeve surrounds said exterior surface adjacent to said first end of said first cylinder, and wherein first securing means are formed on said exterior surface adjacent to said second end of said first cylinder; and

a second cylinder having second securing means formed on an interior surface of said second cylinder, such that said second securing means corresponds to and are adapted to fixedly engage said first securing means.

13. The apparatus of claim 12, wherein said first securing means is an annular lip and said second securing means is an annular groove.

14. The apparatus of claim 12, wherein said first securing means is an annular groove and said second securing means is an annular lip.

5 15. The apparatus of claim 12, wherein said cuff is manufactured from a surgical fabric selected from the group consisting of a Dacron® fabric, a Teflon® fabric, a Gore-Tex® fabric, and the like.

16. The apparatus of a claim 12, further comprising:

10 a guiding rod including a rod end piece formed at a first end of said rod, said rod end piece having a plurality of support brackets extending from said rod end piece and a guiding ring affixed to said support brackets, said ring being adapted to engage said second end of said first cylinder, wherein said interior surface of said second cylinder slidably engages an exterior surface of each of said support brackets;

15 a securing member including a rod sleeve which slidably engages said guiding rod, and a sleeve end piece formed on a first end of said rod sleeve, said sleeve end piece having a plurality of securing brackets, which are adapted to engage said second cylinder and which are positioned to interfit with said support brackets; and

20 urging means for sliding said securing member on said guiding rod, whereby said second securing means of said second cylinder are urged into engagement with said first securing means on said first cylinder.

17. The apparatus of claim 12, wherein said urging means comprises a handle, said handle affixed to a second end of said guiding rod and including a grip having a levered projection, such that when said grip is pressed against said handle, said levered projection contacts said securing member and urges said securing member toward said rod end piece.

25 18. The apparatus of claim 12, wherein at least one eyelet is formed on each of said supporting brackets for receiving at least one suture, whereby said guiding ring is guided onto said first cylinder.

19. An apparatus for automatically fixing sutures used in the surgical replacement of a heart valve, comprising:

30 a first cylinder having a first end and a second end and an interior surface and an exterior surface;

a valve sleeve comprising an annular cuff surrounding said exterior surface adjacent to said first end of said first cylinder,

first securing means formed on said exterior surface adjacent to said second end of said first cylinder;

5 a replacement heart valve positioned within said valve sleeve; and

a second cylinder having second securing means formed on an interior surface of said second cylinder, such that said second securing means corresponds to and are adapted to fixedly engage said first securing means.

20 20. The apparatus of claim 19, wherein said first securing means is an annular lip and said second securing means is an annular groove.

21. The apparatus of claim 19, wherein said first securing means is an annular groove and said second securing means is an annular lip.

22. The apparatus of a claim 19, further comprising:

a guiding rod including a rod end piece formed at a first end of said rod, said rod end piece having a plurality of support brackets extending from said rod end piece and a guiding ring affixed to said support brackets, said ring being adapted to engage said second end of said first cylinder, wherein said interior surface of said second cylinder slidably engages an exterior surface of each of said support brackets;

a securing member including a rod sleeve which slidably engages said guiding rod, and a sleeve end piece formed on a first end of said rod sleeve, said sleeve end piece having a plurality of securing brackets, which are adapted to engage said second cylinder and which are positioned to interfit with said support brackets; and

25 urging means for sliding said securing member on said guiding rod, whereby said second securing means of said second cylinder are urged into engagement with said first securing means on said first cylinder.

23. The apparatus of claim 22, wherein said urging means comprises a handle, said handle affixed to a second end of said guiding rod and including a grip having a levered projection, such that when said grip is pressed against said handle, said levered projection contacts said securing member and urges said securing member toward said rod end piece.

30 24. The apparatus of claim 22, wherein at least one eyelet is formed on said supporting brackets for receiving at least one suture, whereby said guiding rod is directed to said first

cylinder.

25. A method for automatically fixing sutures to secure a valve sleeve including an annular cuff and a replacement heart valve to an annulus formed in a patient's heart, comprising the steps of:

5 removing an existing heart valve thereby forming an annulus in the patient's heart;
placing a first cylinder having a first end and a second end and an interior surface and an exterior surface and comprising first securing means formed on said exterior surface adjacent to said second end of said first cylinder, wherein said first cylinder includes a valve sleeve having an annular cuff, such that said annular cuff surrounds said exterior surface adjacent to said first end of said first cylinder;

10 positioning said annular cuff of said valve sleeve in said annulus and securing said cuff to said annulus with a plurality of sutures;

threading said plurality of sutures over said exterior surface of said first cylinder and over an interior surface of a second cylinder, said second cylinder having second securing means corresponding to and adapted to fixedly engage said first securing means of said first cylinder;

15 applying pressure against said first cylinder and tension to said plurality of sutures to ensure a blood-tight seal between said cuff of said valve sleeve and said annulus; and

20 securing said plurality of sutures between said first cylinder and said second cylinder by engaging said first securing means of said first cylinder with said second securing means of said second cylinder.

26. The method of claim 25, further comprising the step of trimming said plurality of sutures at a length in a range of about 3 mm to about 5 mm, above said second cylinder.

27. The method of claim 25, further comprising the step of trimming said plurality of sutures flush with said second cylinder.

25 28. The method of claim 25, wherein said plurality of sutures is in a range of about 18 to 24 sutures.

29. The method of claim 25, further comprising the steps of:

30 positioning a guiding rod including a rod end piece formed at a first end of said rod, said rod end piece having a plurality of support brackets extending from said rod end piece and a guiding ring affixed to said support brackets, wherein said ring is adapted to engage a second end of said first cylinder, to engage said first cylinder and to hold said cuff against said annulus;

positioning said second cylinder, such that said interior surface of said second cylinder
slidingly engages an exterior surface of each of said support brackets of said guiding rod;

positioning a securing member which slidingly engages said guiding rod, and has a rod
sleeve end piece formed on a first end of said rod sleeve, said sleeve end piece having a plurality
of securing brackets, which are adapted to engage said second cylinder and which are positioned
to interfit with said support brackets, such that said securing member engages said second
cylinder;

threading said plurality of sutures through a plurality of eyelets formed on said plurality
of securing brackets; and

urging said securing member on said guiding rod, whereby said second securing means of
said second cylinder is urged into engagement with said first securing means on said first
cylinder.

30. A method for automatically fixing sutures to secure a valve sleeve including an annular
cuff and a replacement heart valve to an annulus formed in a patient's heart, comprising the steps
of:

removing an existing heart valve thereby forming an annulus in the patient's heart;

positioning said annular cuff of said valve sleeve in said annulus and securing said cuff to
said annulus with a plurality of sutures;

placing a first cylinder having a first end and a second end and an interior surface and an
exterior surface and comprising first securing means formed on said exterior surface
adjacent to said second end of said first cylinder, within said valve sleeve, such that said annular
cuff surrounds said exterior surface adjacent to said first end of said first cylinder;

threading said plurality of sutures over said exterior surface of said first cylinder and over
an interior surface of a second cylinder, said second cylinder having second securing means
corresponding to and adapted to fixedly engage said first securing means of said first cylinder;

applying pressure against said first cylinder and tension to said plurality of sutures to
ensure a blood-tight seal between said cuff of said valve sleeve and said annulus; and

securing said plurality of sutures between said first cylinder and said second cylinder by
engaging said first securing means of said first cylinder with said second securing means of said
second cylinder.

31. The method of claim 30, further comprising the step of trimming said plurality of sutures

at a length in a range of about 3 mm to about 5 mm, above said second cylinder.

32. The method of claim 30, further comprising the step of trimming said plurality of sutures flush with said second cylinder.

33. The method of claim 30, wherein said plurality of sutures is in a range of about 18 to 24 sutures.

34. The method of claim 30, further comprising the steps of:

positioning a guiding rod including a rod end piece formed at a first end of said rod, said rod end piece having a plurality of support brackets extending from said rod end piece and a guiding ring affixed to said support brackets, wherein said ring is adapted to engage a second end of said first cylinder, to engage said first cylinder and to hold said cuff against said annulus;

positioning said second cylinder, such that said interior surface of said second cylinder slidably engages an exterior surface of each of said support brackets of said guiding rod;

positioning a securing member which slidably engages said guiding rod, and has a rod sleeve end piece formed on a first end of said rod sleeve, said sleeve end piece having a plurality of securing brackets, which are adapted to engage said second cylinder and which are positioned to interfit with said support brackets, such that said securing member engages said second cylinder;

threading said plurality of sutures through a plurality of eyelets formed on said plurality of securing brackets; and

urging said securing member on said guiding rod, whereby said second securing means of said second cylinder is urged into engagement with said first securing means on said first cylinder.